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on April 12, 2005

Date of Deposit

John C. Freeman, Reg. No.: 34,483

Name of applicant, assignee or
Registered Representative

Signature

Date of Signature



Our File No. 10781-26

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Appln. of: Ioannis Pallikaris et al.

Appln. No.: 10/787,026

Filed: February 25, 2004

For: Device for Separating the
Epithelium Layer from the
Surface of the Cornea of an Eye

Art Unit: 3764

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22323-1450

Dear Sir;

Pursuant to the obligation under 37 C.F.R. 1.56 and in conformance with 37 C.F.R. 1.97-1.99, and more particularly in accordance with 37 C.F.R. §1.97(b), Applicants hereby cite the following references B1 – B187 in the appended tables.

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For the Examiner's convenience, Applicants are enclosing Form PTO-1449 (five sheets).

The current patent application claims priority under 35 U.S.C. § 120 to U.S. Patent Application Serial No. 10/098,167, filed on March 12, 2002. In compliance with 37 C.F.R. §1.98 (a) – (c), information disclosure statements submitted in this U.S. Patent Application Serial No. 10/098,167 did enclose a copy of each correspondingly listed reference as required under 37 C.F.R. §1.98(a)(2) (as modified by the Commissioner's Notice dated October 12, 2004). Accordingly, pursuant to 37 C.F.R. §1.98 (d) (1) and (2), additional copies of the listed references are not required to be submitted in the present Supplemental Information Disclosure Statement. Applicants invite the Examiner to review the contents of the above-mentioned patent application and the art cited therein.

Additionally, Applicants wish to inform the Examiner that cited publications, presentations, drawings, and photos correspond to other commonly assigned US Patent Applications 09/911,356; 10/786,350; and 10/971,727, which are related to the present application.

By submitting this Statement, Applicants are attempting to fully comply with the duty of candor and good faith mandated by 37 C.F.R. §1.56. As such, this Statement is not intended to constitute an admission that any of the enclosed references, or other information referred to therein, constitutes "prior art" or is otherwise "material to patentability," as that phrase is defined in 37 C.F.R. §1.56(a).

Applicants are aware of application numbers for two applications that are not included herewith. After conducting a search, Applicants were not able to find

publications for Serial Numbers DE 59401716 CO and AT 148527 E. It is our understanding that DE 59401716 CO is a German number for a non-published application which relates to European application number EP 659955 B1. With regard to Austrian application number AT 148527 E, we understand that this is Austria's way of recognizing a European publication that designates Austria. The corresponding European number is also EP 659955 B1.

Applicants are not aware of any official English translations for some of the cited references. As such, Applicants are hereby providing brief statements which are drawn solely from their respective English-language abstracts, English-language translated independent claims, and/or the drawings.

In regard to WO 03/026542 A1, based solely on its translated abstract and its drawing, this reference is pertinent because it appears to relate to an eye surgical instrument, especially for Laser-Epithelial Keratomileusis of the cornea of the eye. This instrument includes a blade with an oval-shaped edge to incise the corneal epithelium.

In regard to EP 0 659 955 B1, based solely on the English claims, the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a scaffold structure. The scaffold structure is preferably for working on facades or similar structure with stanchions arranged in parallel to one another which are connected in the manner of a ladder by cross members on which platforms may be suspended at the same level by means of hooks.

In regard to EP 1 350 492 A2, based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a ring-shaped insert which has an open-pored molding made of sintered glass with roughness at its front surface to prevent an eyeball from touching a surface of the insert with more than 10% of its surface. A latch closure attaches the insert to a ring wall. If the shape of the insert conforms to the eyeball, the shape and

intra ocular pressure are unaffected. If the shape of the insert has a greater curvature, the internal pressure is controlled.

In regard to DE 27 50 492 A1 and based solely on the drawings and the attached English language Abstract, this reference is pertinent because it seems to be directed to a test holder for an assembly board. The test holder has a hinged adaptor in which the assembly board is placed, a cassette with pins and a sleeve contact field. The test holder has a supporting frame with an openable guiding device at its front, with a top and a bottom guiding bar or the assembly board to be tested, and an exchangeable adapter on which the tested board can be placed. An exchangeable cassette with test points is movably fastened to a hinged guiding device behind the frame. It contacts certain points of the assembly board, and a sleeve contact field which is also hinged is provided behind the frame for various plugs.

In regard to DE 38 38 253 A1 and based on the drawings and the English language translation of the Abstract, this reference is pertinent because it seems to be directed to a suction ring. The suction ring of the application is intended to fixedly hold the human eye during surgery. Whereas hitherto, only rings without suction permitted the intraocular pressure to remain unchanged or whereas the suction rings used for a desired increase of the pressure comprised a hollow profile that was open towards the inside, the ring of the present application permits secure fixation of the eye without deforming the eyeball or increasing the internal pressure. The ring comprises an outer rectangular profile (1) which carries an inner member (2) that rests against the eye, extends annularly, has a triangular cross-section and leaves two channels via webs (4) between the inner member (2) and the ring wall (1) in order to achieve a reduced pressure. The circularly extending inner wall (2) lying between the two channels rests against the eye and avoids deformation of the eye by the fixing suction. Fixation of the ring on the eye is guaranteed by the two suction channels (3) without it being possible for the eye wall to be drawn into the hollow profile. The suction is generated by an external vacuum source through the hollow handle (6). The central ring

opening (7) can be used to receive additional concentric rings which permit guidance of a knife.

In regard to DE G 93 15 396.1 U1 and based on solely on the drawings, this reference is pertinent because it seems to be directed to a device for testing an automatic blocking hindrance system (ABV – System) found on vehicles.

In regard to DE 100 51 215 A1, it appears to be based on U.S. Publication US 2002/0052614 A1 which claims priority to it. Based solely on the '614 publication, the '215 reference is pertinent because it seems to be related to a blade which includes a carrier member and a foil of amorphous metal joined to the carrier member via an adhesive layer. The amorphous metal forms the cutting edge of the blade. The cutting edge of the blade is formed by a one-sided ground section extending over the carrier material as well as the amorphous metal. The use of the foil of amorphous metal allows the manufacture of an inexpensive blade having a high sharpness and, with respect to the blade body, an exactly defined position of the cutting edge.

In regard to DE 101 19 477 A1 and based solely on the drawings and the attached English language translation this reference is pertinent because it seems to be directed to a LASEK eye surgery device for use in correction of sight defects. The LASEK eye surgery device has a cutter arrangement for correctly positioning a cutter used to open up the cornea so as to be perpendicular to the surface. The LASEK device has a cutting arrangement having a stator with a removable guide for a cutter.

In regard to DE 102 14 917 A1, this reference is claimed as priority to EP 1 350 492 A2, discussed above. Thus, this reference is pertinent because it seems to be directed to a ring-shaped insert which has an open-pored molding made of sintered glass with roughness at its front surface to prevent eyeball touching surface with more than 10% of its surface. A latch closure attaches the insert to a ring wall. If the shape of the insert conforms to the eyeball, the shape and intra ocular

pressure are unaffected. If the shape of the insert has a greater curvature, the internal pressure is controlled.

In regard to DE 102 32 169 A1 and based solely on the drawings and the attached English language Abstract, this reference is pertinent because it seems to be directed to a LASIK device for removal of an epithelial layer from the eye. The LASIK device has a main body and a trepan that is fed through the main body. The LASIK device is sterilized using gamma radiation. The LASIK device is designed as single piece device to facilitate the sterilization method.

In regard to DE 198 47 089 A1 and based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a suction ring for the eye that has a mainly elliptical suction groove open towards the eye. The main axial diameter of the ellipse creates a working area for an eye-laser for example. Part of a partially shaved-off cornea rests outside. The subsidiary axial diameter of the ellipse is such that it runs as closely as possible to the optimal working area. The side facing away from the eye has guide-tracks holding operation aids such as lens or plane.

In regard to DE 200 23 239 U1, this reference is pertinent because it seems to be a German patent that issued from the German Patent Application DE 100 51 215 A1, discussed above. Thus, this reference is pertinent because it seems to relate to a blade which includes of a carrier member and a foil of amorphous metal joined to the carrier member via an adhesive layer. The amorphous metal forms the cutting edge of the blade. The cutting edge of the blade is formed by a one-sided ground section extending over the carrier material as well as the amorphous metal. The use of the foil of amorphous metal allows the manufacture of an inexpensive blade having a high sharpness and, with respect to the blade body, an exactly defined position of the cutting edge.

In regard to DE 201 07 259 A1 and based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a transport system for blood banks. The transportation of blood bags,

hanging rather than lying, keeps them closer together, increasing mechanical handling density. Up to 15 bags occupy a meter length. Space occupancy of two parallel transport paths is very small at 300 mm width. Carriages on rails conveniently transport the bags on hooks. The transport system, described further, is suitable for clean rooms. Construction is modular.

In regard to DE 202 04 635 U1 and based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a scaffold system. The scaffold system has a scaffolding component that has one hook or opening to take a further scaffolding component in a release lock. The two components are held together by a swing clip with a lateral section, with partial elastic distortion which covers the hook or opening at least partially in the closed position, and exposes it when open. The clip has a swing movement in relation to the first scaffolding unit, and grips under the second component at least partially in the locked position.

In regard to DE 297 14 266 U1 and based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a support frame. The frame has vertical stays and triangular jibs. To fix at least one optimum horizontal angular position of each triangular jib a keyed connection is provided between the coupling member of at least one of the arms of the triangular jib and the associated vertical stay. This keyed connection is provided by a projection and a complementary indentation interacting with it. The projection can be a pin fitting into the hole-like indentation or rib fitting into a slit-like indentation. The indentation and rib run parallel to the relevant vertical stay. The optimum horizontal angle in relation to the longitudinal centre line of a work platform is approximately 60 degrees.

In regard to DE 297 12 339 U1 and based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a support frame for a grid or a manhole cover. The support frame has a profiled edging strip to hold the frame and integral leveling screws with large area support heads which support the frame on the ground. The setting of each screw can be

secured by a lock nut. The leveling screws are permanently secured to the underside of the frame with the size of the support sufficient to support the weight of the frame and the insert.

In regard to DE 298 05 538 U1 and based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a handling support for medical blood banks. The handling support has a tower frame (1) with an outer circumference in the upper area at least one blood bag (B). A tube (BS) is connected to the blood bag to hang below it. It has a connector at its lower end to allow fastening of its lower end. There is at least one work station frame which is arranged at the outer circumference of the tower frame with a defined spacing. An automatic stripping station applies a stripping action to the tube. There is further an automatic welding station with a welder so that the tube can be divided into sections. The tower can be mounted on a base and be made of light alloy.

In regard to DE 298 10 603 U1 and based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a garden fence system. The garden fence comprises spars which are pivotally connected to posts (1) via a double-axis pivot connector, where the first axis runs parallel to the longitudinal axis of the posts and the second axis runs normal to the longitudinal axis of the posts. Battens are connected to the spars via a single axis pivot connector. The single-axis connector encompasses a rod-like element passing through the battens and respective spar. The double-axis connector encompasses an angle section and a base plate which is rigidly attached to a post. The first leg of the angle section is connected with a post so as to be pivotable about the second axis. The second leg has a distal surface facing the post which is convexly curved about the first axis. This curved leg can be brought into contact with a concave distal surface of the base plate. Clamps are provided for holding the leg and base plate together.

In regard to FR 2 691 625 A3 and based solely on the drawings and the attached English language Abstract this reference is pertinent because it seems to be directed to a disposable trocar (or trochar). The disposable trochar is made from a fiber-reinforced

plastic produced by injection, compression or vacuum-injection molding, or from a fiber-reinforced crystalline polymer. The plastic used for the trochar is a thermo-setting plastic selected from e.g. polyesters, polyamides, polycarbonates, polystyrenes and copolymer sates of styrene or other monomers or it can be made from a thermoplastic selected from polyesters, melamine epoxy plastics and polyurethanes. The reinforcing fibers can be of glass, at least 5 mm long and 8-50 microns thick, forming 30-75% by vol. of the plastic. The trochar is in the shape of a bar with one end (1) shaped to receive a drainage tube, a curve (4) and a pointed tip (5) at the other end formed by two flat surfaces at an acute angle.

In regard to JP 2002 119532A, it seems to be related to US Patent 6,451,039 and Canadian patent CA 2 355 478 A1. Based solely on U.S. Patent 6,451,039 and Canadian Patent 2 355 478 A1, this reference is pertinent because it seems to be directed to a microkeratome for creating lamellar sections from a biological tissue.

Further, Applicants reserve the right to contest any of these references as prior art against the present application, and Applicants do not believe that the disclosure of these references, even if finally determined to be prior art, anticipates Applicants' invention or that these references make Applicants' invention obvious.

The undersigned attorney hereby states that as governed by 37 C.F.R. 1.97(b), each item of information contained in this Information Disclosure Statement is being filed prior to the mailing of an Office Action on the merits. Accordingly, Applicants submit that no fee is required for this Information Disclosure Statement, however, should any fees under 37 C.F.R. §§1.16 to 1.21 be deemed necessary for any reason relating to these materials, the Assistant Commissioner is hereby authorized to deduct said fees from Brinks Hofer Gilson and Lione account number 23-1925.

Applicants respectfully request the Examiner's consideration of the above reference(s) and entry thereof into the record of this application.

Respectfully submitted,

April 12, 2005
Date



John C. Freeman (Reg. No. 34,438)

FORM PTO-1449 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (use several sheets if necessary)	SERIAL NO.	CASE NO.
	10787,026	10781-26
	FILING DATE February 25, 2004	GROUP ART UNIT 3764
APPLICANTS: Ioannis Pallikaris et al.		

REFERENCE DESIGNATION	U.S. PATENT DOCUMENTS
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EXAMINER INITIAL	DOCUMENT NUMBER	PUBLICATION DATE	NAME	CLASS/ SUBCLASS	FILING DATE
	B1	2,881,500	04/14/1959	C. W. Furness	
	B2	4,346,482	08/31/1982	Tennant et al.	
	B3	4,381,007	04/26/1983	Doss	
	B6	4,417,579	11/29/1983	Soloviev et al.	
	B7	4,646,720	03/03/1987	Peyman et al.	
	B8	4,662,370	05/05/1987	Hoffmann et al.	
	B9	4,662,881	05/05/1987	Nordan	
	B10	4,676,790	06/30/1987	Kern	
	B11	4,688,570	08/25/87	Kramer et al	
	B12	4,715,858	12/29/1987	Lindstrom	
	B13	4,770,172	09/13/1988	L'Esperance, Jr.	
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	B15	4,775,361	10/04/1988	Jacques et al.	
	B16	4,793,344	12/27/1988	Cumming et al.	
	B17	4,838,266	06/13/1989	Koziol et al.	
	B18	4,840,175	06/20/1989	Peyman	
	B19	4,844,060	07/04/89	Krumeich	
	B20	4,865,033	09/12/89	Krumeich et al.	
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	B24	5,108,388	04/28/1992	Trokell	
	B25	5,171,318	12/15/1992	Gibson et al.	
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	B27	5,196,027	03/23/1993	Thompson et al.	
	B28	5,213,720	05/25/1993	Civerchia	
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FORM PTO-1449 LIST OF PATENTS AND PUBLICATIONS FOR APPLICANT'S INFORMATION DISCLOSURE STATEMENT (use several sheets if necessary)	SERIAL NO.	CASE NO.
	10/787,026	10781- 26
	FILING DATE February 25, 2004	GROUP ART UNIT 3764
APPLICANT(S): Ioannis Pallikaris et al.		

B44	5,599,341	02/04/1997	Mathis et al.	
B45	5,613,965	03/25/1997	Muller	
B46	5,630,810	05/20/1997	Machat	
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	FILING DATE February 25, 2004	GROUP ART UNIT 3764
APPLICANT(S): Ioannis Pallikaris et al.		

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APPLICANT(S): Ioannis Pallikaris et al.		

B138	2003/0105521 A1	06/05/2003	Perez		
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EXAMINER INITIAL	DOCUMENT NUMBER	PUBLICATION DATE	COUNTRY	CLASS/ SUBCLASS	TRANSLATION YES	TRANSLATION NO
	B146	WO 01/93791 A1	12/13/2001	WIPO		X
	B147	WO 01/97729 A1	12/27/2001	WIPO		X
	B148	WO 02/06883 A2	01/24/2002	WIPO		X
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	B150	WO 03/026542 A1	04/03/2003	WIPO	X	
	B151	WO 03/061518 A2	07/31/2003	WIPO		X
	B152	EP 0 659 955 B1	01/29/1997	EP	X	
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	B167	DE 201 07 259 U1	12/06/2001	Germany	X	
	B168	DE 202 04 635 U1	09/04/2003	Germany	X	
	B169	DE 297 14 266 U1	12/11/1997	Germany	X	
	B170	DE 297 12 339 U1	01/29/1998	Germany	X	
	B171	DE 298 05 538 U1	07/16/1998	Germany	X	
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	APPLICANT(S): Ioannis Pallikaris et al.	

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B176	Peter P. Purslow, PhD, Wojciech S.S. Kanwatoski, FROCOphth, "Ocular Elasticity," Ophthalmology, Vol. 103, No. 10, October 1996, pp. 1686-1692.
B177	Chen, K-H. et al. "Transplantation of Adult Human Corneal Endothelium Ex Vivo: A Morphologic Study," Cornea, Vol.20, No.7, 2001, pp. 731-737.
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B179	Schwab, I. R. and Isseroff, R. R., "Bioengineered Corneas - The Promise and the Challenge," The New England Journal of Medicine; Vol. 343, No.2, 2000, pp. 136-138.
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B183	EPI-Peeler Drawing by Geuder, Germany, produced from Chris Lohmann presentation, April 2004, One page.
B184	Lohmann, Chris P., MD, PhD, "Epi-Lasik Epi-Tome", presented April 2004, Seville, Spain, 47 pages.
B185	Photo using a light microscope of a blade manufactured by GeBauer, evaluated in Athens, Greece, on or about June 2004, One page.
B186	Soloway, Barrie D., "US Clinical Studies with the EpiK for E-Lasik" performed by Moria (Epi-Lasik and Lamellar Surgery), presented September 18, 2004, Paris, France, Twenty-three pages.
B187	Gebauer announcements of clinical results for the first 100 Epi-LASIK patients treated in Europe, March 5, 2004, One page.

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